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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,409	06/05/2001	Markus H. Frank	81994/279322	1825

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,409

Applicant(s)

FRANK ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-26 and 30-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-26 and 30-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☒ Other: *sequence alignment*.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-01-2003 has been entered.

Claims 18-26, and 30-40 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Claim 39 and 40 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites "vector **comprising a distinct coding element consisting of**" but it is not clear what the metes and bounds are for the limitation.

Applicant argues that "vector" is a well understood term, therefore not indefinite. The argument is fully considered but found unpersuasive because the Office did not reject the claims under 35 U.S.C. 112, second paragraph because of the limitation "vector" but rejected because the limitation copied in bold above. First, it is not clear which transitional phrase "comprising" or "consisting of" controls the scope of the

claims. See MPEP 2111.03 for transitional phrases. Second, does the scope of claim limited to vector encoding protein consisting essentially of SEQ ID NOs 1-8, or does fragments of said protein also within scope of the claims? The second question is raised due to the limitation "comprising a distinct coding element". If a fragment is included in the scope of the claims, then the claims do not further limit the base claim. "Expression vector comprising the polynucleotide of..." would obviate the rejection if the scope of the claims is a expression vector encoding SEQ ID NOs 1-8 as applicant appears to argue by saying that vectors mean element with restriction sites, promotor, a site for controlling translation" at page 5 last paragraph of the response filed on 10-01-2003.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-26, 30-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This written description rejection is based on the definition of the term "consisting essentially of" at page 6 of the specification as **"the term is meant to encompass proteins having exactly the same amino acid sequences, as well as proteins with insubstantially different sequences, as evidenced by their possessing the same basic functional properties."** Consisting

essentially of a specified protein sequence, for example SEQ ID NO:1 usually means a few more amino acids attached at the N-terminal or C-terminal end of said protein for example, N-terminal His tag to SEQ ID NO:1. However, "consisting essentially of" defined in the instant specification appears to encompass amino acid changes in anywhere in a given sequence; for example, Glu at amino acid # 60 instead of Asp of SEQ ID NO:2 could encompass a polynucleotide encoding a protein essentially of an amino acid sequence of SEQ ID NO:2 as long as the change does not affect the basic functional properties. Therefore, the claims are interpreted as drawn to a genus of polynucleotides encoding proteins structurally similar to SEQ ID NOs 1-8 as long as said proteins have insubstantially different sequences, as evidenced by their possessing the same basic functional properties. The claims do not specify what kind of basic functional property each of the prototype i.e. SEQ ID NO:1-8 might possess.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is SEQ ID NO:2 and hypothetical sequences represented by SEQ ID NOs 1, 3-8. There is not even identification of any particular portion of the structure that must be conserved in order to retain the basic functional properties. Accordingly, in the absence of sufficient recitation

of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, given that the specification has only described SEQ ID NO: 2 and hypothetical SEQ ID NOs 1, 3-8 (see line 20-21 of page 17 of the specification, which says “the predicted proteins”). Therefore, polynucleotide encoding the amino acid sequence set forth in SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

A definition by function alone “does not suffice, to sufficiently describe a coding sequence “because it is only an indication of what the gene does, rather than what it is.” *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406.

Dependent claims are rejected because they depend on the rejected base claims.

Claim Rejections - 35 USC § 101

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 40 is newly rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 40, as written, do not sufficiently distinguish over a host cell as it exists naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as suggested at page 11 lines 16-23 of specification. See MPEP 2105.

Claim Rejections - 35 USC § 101

Claims 18-26, 30-40 **remain rejected** for reason of record under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, and a credible asserted utility or a well established utility. The rejection of claim 20 drawn to isolated polynucleotides encoding SEQ ID NO:2, claim 32 drawn to SEQ ID NO:10, would be withdrawn when the claims are limited to the specific sequences. However, the claims as presented are rejected because they are dependent on the rejected base claims.

Applicant's arguments and Dr. Frank's declaration with the new experimental data have been fully considered. However, this rejection is maintained because neither

applicant's argument nor Dr. Frank's declaration addresses the Office's rejection of utility for the claimed polynucleotides encoding SEQ ID NOs 1, 3-8, or SEQ ID NO:9, 11-16. Applicant's argument and Dr. Frank's declaration with the new experimental data are directed to utility of SEQ ID NO:2. However, the claims are not limited to polynucleotide encoding SEQ ID NO:2.

Frank et al (Nov. 2003, J. Biol. Chem. vol. 47, pages 47156-65) at Fig. 1 teach that SEQ ID NO: 2 is translated from 2906-bp cDNA. For the record, the Office notes that the instant specification does not teach the experimentally determined 2906-bp cDNA encoding SEQ ID NO:2. Note the sequence alignment. The closest to the 2906-bp cDNA encoding instant SEQ ID NO:2 is SEQ ID NO:10, which appears to contain either erroneous sequences or intron sequence. None of those other sequences i.e. SEQ ID NO:9, 10-16 encodes instant SEQ ID NO:2, unlike instant specification at page 3 lines 15-27 speculates.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
December 21, 2003


MISOOK YU
TECHNOLOGY CERTIFICATION